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EXAMINER	
KINGAN, TIMOTHY G	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,563	PETERS ET AL.	
	Examiner	**Art Unit**	
	TIMOTHY G. KINGAN	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _15 September 2009_.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-23, 27 and 51-53_ is/are pending in the application.

4a) Of the above claim(s) _51-53_ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-23 and 27_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

2. Newly submitted claims are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The inventions as claimed are of materially different structural design, in that the invention claimed in original Group I (claims 1-23 and 27) requires a first channel with inlet and outlet and second channels branching sequentially from the first channel, while the inventions of independent claims 51 and 52 provide third channels downstream of the second channels and a stopping means between the second and third channels and, by virtue of such third channels, appear to have a different mode of operation, function or effect.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 51-53 are withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. **Claims 1-23 and 27** are rejected under 35 U.S.C. 103(a) as being unpatentable over S.E. McBride, U.S. Patent 6,395,232 (herein after McBride) in view of C.C. Karp, U.S. Patent Application Publication 2003/0005967 (herein after Karp) and M. Seki et al., U.S. Patent Application Publication 2002/0195463 (herein after Seki).

For Claims 1, 5, 9 and 23, McBride teaches a microfluidic fluid delivery and distribution system having a fluid input (abstract), **46** coupled to a reservoir **14** and a main channel **48** which in turn has various branches **50** (first channel with inlet, divided into sections defined by branch channels, thereby forming a first channel system) fluidically connected to reaction wells (col 5, lines 36-47; Figs. 5-7) (first channel with inlet, second channels with predetermined volume branching sequentially from the first channel), the channel systems organized as a multiple sample processor or microfluidic device **16** comprising a layered structure with multiple first and second channels (col 1, lines 62-67) (a sample carrier having a microfluidic arrangement). McBride also teaches the second channels fill sequentially from the closest to the most distant with respect to the fluid input (col 5, lines 62-65).

While McBride is not specific with respect to the distribution of capillary forces in the microfluidic system, McBride does disclose that fluids may be moved through the fluidic system by draining or capillary action, as well as pumping (col 4, lines 25-28) (second channels have a greater capillary force than the third channels). From such teaching, together with the sequential filling of second channels, it would have been obvious to one of ordinary skill in the art to provide greater capillary force at the nodes of first with second channels in order to attain the sequential filling of second channels

prior to filling of new first channel segments. Further, from the teaching of sequential filling it appears that differential capillarity at branch points is an inherent feature of the distribution system.

With respect to the limitation that fluids not mix when exiting the microfluidic system, McBride teaches a layered system in which the bottom layer **9** holds reagents and other materials in wells **15** for reaction or synthesis (col 3, lines 48-50; Fig. 2) (liquids exiting the second channels do not mix).

McBride does not teach the first channel has one outlet. However, McBride does teach that the main channel may be provided with a second input **46''** to overcome the pressure drop from the input to the branch points (col 6, lines 28-32). Examiner notes that such second input may also function as an outlet of the first channel. Moreover, use of such single outlets of main channels in fluid distribution systems comprising sequential branched channels is known in the art. Karp teaches systems for metering microfluidic volumes (abstract) comprising a single outlet port **311** serving a trunk channel **313** filling branch channels **314** ([0055]; Fig. 1A). It would have been obvious to one of ordinary skill in the art to use an outlet in order to provide an adequate vent for gas being pushed through the main channel as it is filled with fluid from the reservoir.

While McBride and Karp do not specifically teach the capillarity in the area of the outlet with respect to the inlet, as noted above, McBride does teach that force in fluid flow may be provided by capillary action. Further, the use of capillarity in directing flow is known in the art. Seki teaches microchips for use in flow distribution with first and third flow channels [0054] (first and second channels), and that liquid introduced into the

inlet is drawn into the channel by a capillary phenomenon [0085]. Therefore, it would have been obvious to one of ordinary skill in the art, seeking to solve the problem of moving fluids in a distribution system, to provide sufficient capillarity at an outlet and at branch points in a sequential filling system such as those of McBride, Karp and Seki in order to ensure an acceptable rate of filling within the design needs of use of the device.

For Claim 2, McBride and Karp do not teach changing geometrical properties of the walls at the branch points. However, use of such physical feature in directing fluid flow is known in the art. Seki teaches that liquid is pulled through the first channel into and through the third channel from top to bottom by virtue of changing cross sectional area (changing geometric properties at the transition from the first to the second channel) [0087]-[0089], but when the liquid reaches the bottom of the third channel is does not pass out, by virtue of changing cross sectional areas (second channels begin at branch points and end a means for stopping liquid flow) [0090]-[0091]. It would have been obvious to one of ordinary skill in the art to use a changing cross sectional area in the device of McBride and Karp, in addition to or in the alternative to changing capillarity, in order to provide the known advantages with respect to directing fluid flow, according to the teaching of Seki.

For Claim 3, McBride, Karp and Seki do not specifically teach the relative capillarity at the branch points of first and second channels. However, Seki does teach the third flow channel may be made hydrophilic (with respect to the first channel) as a control mechanism for liquid flow [0030] (a change in surface property of the walls at the transition for the purpose of directing fluid flow). It would have been obvious to one of

ordinary skill in the art, from such teaching, to use a change in the hydrophilicity at the intersection of first and second channels in order to use the well known property of boundaries with respect to hydrophilicity or hydrophobicity to direct flow.

For Claim 4, McBride teaches the branch channels **50** have a capillary break **56** (col 5, lines 49-51).

For Claim 6, McBride, Karp and Seki do not teach the capillarity of the reservoir with respect to the first channel. However, McBride teaches that capillarity may provide force for movement of fluid (col 4, lines 25-28). Therefore, it would have been obvious to one of ordinary skill in the art to provide such relative capillarity in order to move fluid out of the reservoir and into the first channel.

For Claims 7 and 8, McBride and Karp do not teach an outlet reservoir. However, such reservoirs are known in the art. Seki teaches a first flow channel having first and third ports for charging or discharging liquids ([0055], Fig. 2a. 16, 22, 18a and 18c) (first channel has one inlet and one outlet, the inlet reservoir upstream of the inlet to the first channel and the outlet reservoir downstream of the outlet of the first channel). It would have been obvious to one of ordinary skill in the art to provide an outlet reservoir in order provide for overflow, thereby reducing a requirement for precision during filling at the inlet. Further, as noted above, both McBride and Seki teach use of capillarity in directing flow. Therefore, it would have been obvious to one of ordinary skill in the art to provide such relative capillary in order to attain or ensure the desired directionality in flow during fluid distribution.

For Claim 10, McBride, Karp and Seki do not teach increasing capillarity of the first channel sections from inlet to outlet. However, consistent with the teaching of McBride and Seki on use of capillarity in directing fluid flow, it would have been obvious to one of ordinary skill in the art to use such gradient of capillarity in design cooperation with the capillarity at the branch points and of the second channels, in order to provide for, ensure and optimize sequential filling of the first branch channel in a method that fills to a capillary break or other desired stopping point of a second channel and then proceeds with filling of the second branch channel. Examiner notes that, from the teaching of McBride on sequential filling, such relative capillarities are apparently an inherent feature of the system.

For Claims 11, 12, 15 and 16, McBride teaches that branches **50** have a cell feed **54** and a capillary break **56** (col 5, lines 49-51) (second channels divided into sections to form a system, such system provide with a stopping means comprising a capillary break or stop). McBride does not teach the relative capillarity of the sections, only that such sections fill sequentially. From such teaching, it appears that a constant or increasing capillarity is an inherent feature of the second channel system.

With respect to the stopping means comprising a microvalve in claim 16, examiner notes that a valve is a “device that controls movement of liquids or gases through pipes or passages” (quoted from dictionary); therefore, the capillary break in the teaching of McBride, operating to stop the flow of liquid, meets the claim.

For Claims 13 and 14, McBride teaches that each second channel **50** is fluidically coupled beyond the capillary break with a single reaction well **52** (one third channel at a

time is connected to the stopping means) (col 5, lines 38-43). McBride is silent on the relative capillarity of the third and second channels. However, it appears that a change in capillarity is not required in the fluid delivery system of McBride, which employs a low pressure subsystem for transport into reaction wells **52** (col 5, lines 52-56). Therefore, it would have been obvious to one of ordinary skill in the art to use a capillarity in the third channel unchanged from that in the second channel in order to minimize unnecessary design features.

For Claim 17, McBride teaches that each reaction well **52** (third channel) has one outlet in the direction of fluid flow (Figs. 5-7).

For Claim 18, McBride, Karp and Seki do not teach the second outlet having a microvalve or capillary stop. However, it would have been obvious to one of ordinary skill in the art to use such valves to provide for movement of liquid in filling the reaction chamber (third channel) but not beyond, in order to prevent overfilling or discharge of a reaction product forming in the third channel prior to completion of such reaction.

For Claim 20, McBride teaches the inclusion of reaction wells **52** downstream of the second channels (col 5, lines 40-43; Figs. 5-7) (third channels made as cavities).

For Claim 27, McBride, Karp and Seki do not teach the second channel with a cavity in the form of a recess. However, McBride teaches such second channels comprise a "cell feed" and a capillary break (col 5, lines 49-51). It would have been obvious to one of ordinary skill in the art to use a cavity or recess for such cell feed to serve the need for an adequate volume for a reaction or separation (col 4, lines 30-32) occurring in downstream reaction well (third channel).

3. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over McBride, Karp and Seki as applied to claim 1 above, and further in view of P. Andersson and G. Ekstrand, U.S. Patent Application Publication 2003/004322 (herein after Andersson) and G. Kellogg et al., U.S. Patent Application Publication 2002/0150512 (herein after Kellogg).

For Claim 19, McBride, Karp and Seki do not teach meander-shaped channel systems of outlet reservoirs. However, such structures are known in the art. Anderrson teaches meander-form microconduits ([0145] Fig. 3a, 301) (first channel system) as well as second channel system (Fig. 2a, 202). Further, Kellogg teaches such curved channels can reduce the incidence of aerosol production [0254]. It would have been obvious to one of ordinary skill in the art to use the meander-shaped channels of Anderrson in the device of McBride, Karp and Seki in order to reduce aerosol production, according to the teaching of Kellogg, or to provide for improved packing efficiency of longer channels or to provide control over capillarity.

4. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over McBride, Karp and Seki as applied to claim 1 above, and further in view of M. Jakobsen and L. Kongsbak, U.S. Patent Application Publication 2003/0152927 (herein after Jakobsen). McBride, Karp and Seki do not teach inclusion of absorbent material in channels or the outlet reservoir. However, use of absorbent material is known in the microfluidic art; Jakobsen teaches closed analysis slides with channels (microfluidic

devices) and inclusion of absorbent material in the waste area of such devices for soaking up waste fluid and preventing backflow. It would have been obvious to one of ordinary skill in the art to use the absorbent material of Jakobsen in the device of McBride, Karp and Seki in order to provide the known advantages as taught by Jakobsen or to promote directionality of fluid flow.

5. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over McBride, Karp and Seki as applied to claim 1, above, and further in view of Andersson.

For Claim 22, McBride, Karp and Seki do not teach aeration channels at a branch point in the first channel. However, Anderrson teaches the importance of venting microconduits to allow displacement of air with incoming liquid [0100]. Further, Anderrson teaches multiple inlet vents intersecting the first channel and connected to ambient via a common venting channel ([0116]; Fig. 2a, 208 and 209) (aeration channel in the first channel in the area of a branch point). It would have been obvious to one of ordinary skill in the art to use the venting means of Anderrson in the device of McBride, Karp and Seki in order to provide for displacement of air with incoming liquid, according to the teaching of Anderrson.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY G. KINGAN whose telephone number is (571)270-3720. The examiner can normally be reached on Monday-Friday, 8:30 A.M. to 5:00 P.M., E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TGK /Jill Warden/
Supervisory Patent Examiner, Art Unit 1797